EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-11-020	Base: 02/01/2011 To 01/31/2014 — Option Period Number: 2	EDSP Study & Review

Contractor: CAMBRIDGE ENVIRONMENTAL, INC.

Specify Section and paragraph of Contract SOW: Task A

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 02/01/2013 To 01/31/2014

Comments:
In accordance with contract clause B.2 "Work Assignments", please submit a detailed work plan and cost estimate to the Contracting Officer (CO)and Contracting Specialist (CS) within fourteen (14) calendar days after receipt of this work assignment initiation. The work plan shall include a detailed technical and staffing plan with incorporated QA elements.

☐ Superfund — **Accounting and Appropriations Data** — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
02/01/2011 To 01/31/2014		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-305-6937	
	FAX Number:	
Project Officer Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-305-6937	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Goshell (Signature) 2-8-13 (Date)	Branch/Mail Code:	
	Phone Number: 202-564-4353	
	FAX Number:	

Contract #EP-W-11-020

Work Assignment # EP-2-06

Statement of Work

I. Title: EDSP Study Review and Support Activities

IIa. Project Officer (PO)/Work Assignment Manager(WAM):
Tanisha Brockett (7507P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

IIb. Alternate Project Officer (APO):
Derek Scott (7507P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

IIc. Alternate WAM:
Brian Montague
1200 Pennsylvania Avenue, NW
Washington, DC 20460

III. Period of Performance: February 1, 2013 – January 31, 2014.

IV. Level of Effort: 2200 hrs.

V. Background:

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups.

EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship

between the dose and the E, A, or T effect. In some cases, other guideline studies, non-guidelines studies, or Other Scientifically Relevant Information (OSRI) may be submitted to provide information of possible interest.

VI. Scope of Work:

Under Task A of the Contract's Statement of Work, the Contractor shall provide support primarily in the area of review and evaluation of available data pertaining to the effects, chemistry, and fate of pesticides or other chemicals (including the evaluation of environmental monitoring data), assessing environmental risk from pesticides and other chemicals, and the assessment of pesticide or other chemical effects, fate, and transport in the environment. This Work Assignment will focus exclusively on studies submitted as part of the Endocrine Disruptor Screening Program (EDSP), and may include the use of special software provided by EPA designed to produce Data Evaluation Records (DERs). The contractor is responsible for procuring and maintaining any necessary software, including statistical packages, needed to perform the work according to Agency instructions.

Under Task A, the primary task under this Work Assignment for the current Option Year (OY2) will be to conduct primary reviews of screening level (Tier 1) EDSP assays performed according to Office of Chemical Safety and Pollution Prevention (OCSPP, formerly OPPTS) Guideline 890.1100 (Amphibian Metamorphosis Assay) and 890.1350 (Fish Short Term Reproduction Assay) and to prepare DERs to document these reviews. The expected level of effort (LOE) for primary review and DER preparation, together, is 25 hours per Amphibian Metamorphosis Assay and 40 hours per Fish Short Term Reproduction Assay. EDSP policies and procedures, including relevant test guidelines, SEPs, and DER templates (also called "Study Profiles"), are publicly available online at **http://www.epa.gov/endo**.

The Contractor shall use the statistical software package, Comprehensive Environmental Toxicity Information System (CETIS), according to the terms specified and guidance provided in the document entitled, *CETIS Support Document 00 - EFED CETIS Release Memo 122012.pdf*, The Contractor shall be responsible for acquiring, running and maintaining the same version of the CETIS software program that EFED is currently using and will coordinate with the WAM as required; The Contractor will receive and utilize updated backend database files (i.e. ".mdb files") containing additions or modifications as needed, (e.g. test types, decision trees, templates, etc.) and will utilize applicable, current support documentation (e.g. EFED CETIS User Guide and CETIS Support Documents). The Contractor will fully substantiate and document all work efforts in this regard so that EPA may critically analyze and approve/disapprove any recommendation, options, alternatives or courses of action flowing from the Contractor's work effort.

Under Task A, the Contractor shall, upon request by EPA, review other effects, fate, and transport studies provided to the Contractor by EPA and shall collect and review data from the open literature or from other sources designated by EPA. The reviews shall: (1) evaluate individual studies of chemicals subject to the EDSP and identify any variance from published guidelines/standard evaluation procedures (SEPs)/data review guidelines, etc., (2) evaluate data from the open literature or other sources when specifically requested by EPA, and (3) review and synthesize information from multiple data sources as designated by EPA.

Under Task A, the Work Assignment Manager (WAM) or Project Officer (PO) will make available to the Contractor the studies (for preparation of a DER), any supplemental data files, and other information to be reviewed, with the occasional exceptional circumstance where the Project Officer requests that the Contractor collect and aggregate extant data or studies from open literature or other sources. The studies and data will be provided in electronic or printed form (originals or reprints of each study). Due dates for each data package and/or assessment and/or project shall be negotiated between the Project Officer (Agency) and the Project Manager (the Contractor).

Under Task F, Contractor support may be requested for additional activities related to software and/or databases to be used under the EDSP; these activities may include but are not limited to beta testing of applications, quality assurance/quality control (QA/QC), data entry, and preparation of reference materials, as needed. In the current OY, the Contractor will be asked to conduct beta testing of a web-based application called a DER Composer, which provides an interface for entering DER information, allows the input information to be saved and reloaded, and produces output files that convey the DER information in the form of (1) a document file and (2) a data file that can be imported into a database. The Contractor will be asked to beta test a DER Composer specific to the Fish Short-Term Reproduction Assay. The format of the DER Composer is similar to the DER template for this study, which the Contractor will already be using to prepare DERs under Task A. Beta testing efforts will include (1) testing file functions, such as loading and saving files, (2) entering DER information into the DER Composer interface, (3) providing feedback on the general functionality of the DER Composer, (4) comparing the format and content of the DER Composer interface with the DER Template for the Fish Short-Term Reproduction Assay, and (5) comparing the format and content of information entered into the DER Composer with the document file output. The Contractor will be asked to beta test the DER Composer using information from four separate studies; in other words, the Contractor will conduct four individual tests. The expected LOE for beta testing the DER Composer is 20 hours per study, equal to 80 hours for four studies, beyond any hours used for conducting a primary review of each study as previously described in this WA under Task A.

Under Task F, the Contractor may be asked to perform data entry in a specific format or into a specific database, as designated by the Agency. The Contractor will be responsible for performing QA/QC of such data in accordance with EFED's Quality Criteria, as described below in Section VII. This data entry activity is separate from the preparation of DERs as described under Task A. The anticipated LOE for data entry and associated activities in the current OY is 210 hours.

Under Task F, the WAM or PO will make available to the Contractor the test version of the DER Composer for beta testing via an internet link.

The Contractor will fully substantiate and document all work efforts in this regard so that EPA may critically analyze and approve/disapprove any recommendation, options, alternatives or courses of action flowing from the Contractor's work effort.

Communications shall take place as necessary to resolve technical, format and entry questions. Communication may be via phone calls, FAX, E-mail, and/or other types of progress reports. Face-to-face meetings or conference calls will be held as deemed necessary.

VII. Deliverables:

As mentioned in the Scope of Work, the due date will be negotiated between the Project Officer (EPA/EFED) and the Project Manager (Contractor). A standard review of a study performed according to OCSPP Guideline generally takes twelve weeks after receipt to complete. However, on occasion, the Contractor will be required to perform an enhanced review. This enhanced review will require that the due date and/or schedules be changed or accelerated. Enhanced review of studies and data is required under Section 33 of FIFRA (as added by subsection (f)(2) of the Pesticide Registration Improvement Act of 2003). Delivery of DER Composer beta testing results is expected four weeks after the Contractor receives access to the test application. Completion of any additional data entry services and delivery of associated files (if any) is expected four weeks after the Contractor receives the data source file(s) and the task is initiated, as negotiated by the Project Officer.

Deliverables, including but not limited to DERs, may be delivered electronically via secure file transfer protocol (FTP) site, as designated by the Agency. When necessary, deliverables will be accepted via email or by courier or Federal Express. Deliverables sent by courier or Federal Express shall include the hardcopy and a CD. When submitting deliverables electronically, such as by FTP, email, or on CD, the submission will include any input or output files used for statistical analysis, detailed calculations (such as a spreadsheet) that support the analysis in the DER, any input and output files for software (DER Composers) that may be used to create the DER (including XML files, if applicable), and any requested electronic data entry submissions, in addition to the DER or other primary deliverable. A hardcopy of the associated Green Sheet shall accompany the DER. The deliverables for beta testing of the DER Composer will include a spreadsheet that documents each component of the test with each study, screen shots of any error messages or problems encountered, and input and output files for each individual test.

Quality Criteria:

The contractor shall submit all deliverables in Microsoft Word® (*.docx) and Excel (*.xlsx or *.xlsxm), unless otherwise specified. Input files may be provided in the file format (*e.g.*, ASCII, CSV, XML, *etc.*) used with the designated software. All tables, graphs, diagrams, etc. shall be developed using programs that allow for them to be easily imported into, and edited within, Microsoft Word® and Excel. All deliverables shall be clearly written, concise, and free of spelling and grammatical errors. (Note: Although EFED understands that there are nuances in spelling and grammar that may prevent documents from being 100% error free, there must be evidence that, at a minimum, a spell and grammar check was run, and that the Contractor made an honest effort to produce error-free deliverables for EFED.)

Unless otherwise stated in a technical direction SOW, EFED's minimum data quality criteria are 1) > 95% accuracy in all data summarization table entry, where all values and their accompanying units entered by the contractor into the summarization tables match exactly with those in the source data (e.g. DERs) 2) >95% accuracy between text and data tables, so that any

values and their units referenced in the text are identical to those that appear in the data summarization tables, and 3) all relevant data and interpretation thereof correspond to the format and language style of any example(s) provided, to the extent instructed by EFED. Any electronic data spreadsheets provided to the contractor as supplements to a study report should be cross-referenced, by the contractor, with the certified data in the study report to ensure accuracy.

It is expected that the contractor shall approach each assignment as being unique; therefore, wherever examples, template, formats, etc. have been provided, the contractor shall generally follow them in such a way to ensure that all salient points pertaining to the particular chemical being assessed are included or added.

VIII. Reporting Requirements:

A Work Plan shall be submitted within 14 days of receipt of the approved Work Assignment as required in the contract. A final Work Plan shall be submitted within 5 days of receiving comments on a proposed Work Plan. A Work Plan is a formal document describing in comprehensive detail the necessary technical activities, staffing requirements, and QA/QC activities that shall be implemented to ensure that the results of the work performed will satisfy the needs and quality criteria identified in the Work Assignment and this Technical Direction. The staffing plan shall be written in accordance with all applicable elements (i.e. A1-A9, B9, B10, C1-C2, and D1-D3) of the EPA/QA R-5 document, EPA Requirements for Quality Assurance Project Plans, in consultation with the EPA/QA G-5 guidance document (USEPA, 2001; 2002). Within the staffing plan, the contractor shall clearly identify any points of clarification or additional information needed, which were not already addressed in the SOW. This work plan shall also clearly indicate the contractor's proposed staffing levels and cost estimates for the work to be performed under this technical direction. The contractor shall indicate any proposed modifications to the time frames specified by EFED, with reasons for the proposed changes.

Written monthly progress reports shall include a detailed breakdown of costs and hours by task, and a description of tasks which were initiated or completed, and any problems which arose, as required in the contract.

IX. Schedule of Deliverables:

Work Plan	14 days after receipt of WA
Revised Work Plan	5 days after receipt of comments
DERs for Tier 1 EDSP studies	12 weeks after receipt of each study
Beta Testing of DER Composer	4 weeks after receipt of link to test application
Additional Data Entry	4 weeks after receipt of data source

The anticipated schedule for providing Tier 1 EDSP studies to the Contractor for review under Task A is as follows.

Timeframe	**OCSPP Guideline**	**Number of Studies**
February – March 2013	890.1100 Amphibian Metamorphosis Assay	
	890.1350 Fish Short-Term Reproduction Assay	

April – June 2013	890.1100 Amphibian Metamorphosis Assay
	890.1350 Fish Short-Term Reproduction Assay
July – September 2013	890.1100 Amphibian Metamorphosis Assay
	890.1350 Fish Short-Term Reproduction Assay
October – December 2013	890.1100 Amphibian Metamorphosis Assay
	890.1350 Fish Short-Term Reproduction Assay

Approximate Total Number of Tier 1 EDSP studies to be reviewed in the current OY

890.1100 Amphibian Metamorphosis Assay	30
890.1350 Fish Short-Term Reproduction Assay	60

The timeframe for initiating beta testing of the DER Composer and any additional data entry services under Task F will be negotiated between the PO and the PM.

X. Travel:

No travel is anticipated

XI. Management Controls:

All duplication shall be in accordance with clause H.2 (Printing) of the contract. All technical direction shall be issued by the WAM in accordance with clause H.16 of the contract.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-11-020	02/01/2011 To 01/31/2014 Base Option Period Number 2	EDSP Study & Review

Contractor: CAMBRIDGE ENVIRONMENTAL, INC.

Specify Section and paragraph of Contract SOW: Task A

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 02/01/2013 To 01/31/2014

Comments:
The purpose of this action is to approve the contractors Work Plan and Cost Estimate dated 3/26/2013 for 2,200 hours at a cost of $217,162.80.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 02/01/2011 To 01/31/2014	$0.00	0
This Action:	$217,162.80	2,200
Total:	$217,162.80	2,200

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 03/26/2013	$217,162.80	2,200
Cumulative Approved:	$217,162.80	2,200

Work Assignment Manager Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-305-6937	
	FAX Number:	
Project Officer Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-305-6937	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell Jody Gosnell (Signature) 3-29-13 (Date)	Branch/Mail Code:	
	Phone Number: 202-564-4353	
	FAX Number:	